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Low Dose Furazolidone for Eradication of H- pylori Instead of Clarithromycin: A Clinical Trial

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Abstract

Background: Helicobacter pylori infection is a common chronic human bacterial infection. Triple- therapy regimen containing a proton pump inhibitor, clarithromycin, and either amoxicillin or metronidazole is commonly used as first-line treatment for its eradication. However, it may not provide the acceptable eradication rate. The present study was designed to evaluated efficacy of low dose furazolidone with amoxicillin and omeprazole for eradication of H- pylori.

Materials and Methods: One hundred twenty patients with non- ulcer dyspepsia or peptic ulcer confirmed by upper GI endoscopy, plus H- pylori infection confirmed by rapid urease test were included in the study. They were randomly divided into two groups, and then received clarithromycin, amoxicillin, and omeprazole, or furazolidone (100 mg PO bid), amoxicillin, and omeprazole. They were evaluated using urea breath test at the end of the study.

Findings: The eradication rates were 57.6% and 78.8% in clarithromycin and furazolidone groups, respectively. Their difference was statistically significant (P value 0.013). No side effect was seen in the furazolidone group.

Conclusion: Low dose furazolidone rather than clarithromycin can be used as low- cost and effective drug for eradication of H- pylori, in combination with amoxicillin and omeprazole.

Keywords: Helicobacter pylori, furazolidone, non- ulcer dyspepsia, peptic ulcer

1. Introduction

Helicobacter pylori (H- pylori) infection is one of the most common chronic human bacterial infections. It is responsible for the most frequent and persistent bacterial infections worldwide. H- pylori infection affects nearly half of the world's population (Garza-González, Perez-Perez, Maldonado-Garza, & Bosques-Padilla, 2014). The consequences of the infection are chronic gastritis, gastric and duodenal ulcers, gastric cancer, and primary gastric lymphoma of mucosa-associated lymphoid tissue type (MALT lymphoma). Eradication of H- pylori may cure dyspepsia, peptic ulcer disease, and MALT lymphoma (Peedikayi, AlSohaibani, & Alkhenizan, 2014).

The treatment programs for the implementation of H- pylori eradication therapy should be based on patient compliance, antibiotic medication history, and local antibiotic resistance. The common treatment programs included triple therapy, quadruple therapy (containing bismuth), sequential therapy, concomitant therapy with proton pump inhibitor (PPI) and amoxicillin, clarithromycin and metronidazole for 10–14 days (Rongli & Liya, 2014). However, H- pylori eradication treatments following these regimens produce cure rates lower than 80%, mainly due to an increase in clarithromycin resistance (Chuah, Tsay, Hsu, & Wu, 2011; Ayala, Escobedo-Hinojosa, de la Cruz-Herrera, & Romero, 2014). Multiple bacterial factors are influencing eradication therapy success rate, with the development of resistance to antibiotics as the most important. Moreover, poor patient compliance due to adverse reactions to the medications, the cost of the drugs, or patient difficulties complying with the therapy regimen should not be ignored (Song &Ang, 2014). Recently, the efficacy of triple therapy decreased globally due to the increased rate of clarithromycin resistance (Talebi Bezmin Abadi, 2014). A recent multicenter study showed that resistance rates have been 17.5% for clarithromycin, 14.1% for levofloxacin and 34.9% for metronidazol (Kanizaj & Kunac, 2014). So, investigation for other treatment regimens has been noticed (Federico, Gravina, Miranda, Loguercio, & Romano, 2014).

Furazolidone is a synthetic nitrofuran derivative with bactericidal or bacteriostatic activity against Gram-positive and Gram-negative bacteria. It is well absorbed in the intestine with no tissue accumulation. It has been used for eradication of H- pylori in earlier studies in combination with other drugs as second or third line therapy (Isakov, Domareva, Koudryavtseva, Maev, & Ganskaya, 2002; Eisig et al., 2005; Machado, da Silva, & Viriato, 2008; Cheng & Hu, 2009). One of the great impediments regarding the use of furazolidone is its association with significant adverse effects (Isakov et al., 2002; Eisig et al., 2005; Eisig et al., 2009). Then, can we use lower dose of the drug to avoid its side effects?

The present study was designed to evaluate efficacy of a lower dose of furazolidone in eradication of H- pylori as first-line therapy in patients with peptic ulcer disease and non-ulcer dyspepsia compared to clarithromycin.

2. Materials & Methods

2.1 Materials Studied

One hundred twenty patients older than 15 years were chosen from endoscopy ward of a teaching hospital in Qazvin City, Iran for the study. They were referred for upper GI endoscopy by their treating physicians due to GI symptoms. Rapid urease test had been performed for them and were positive. Their endoscopic diagnosis was peptic ulcer disease or non-ulcer dyspepsia. Any patient with past history of previous GI surgery, cigarette smoking, pregnancy, hemolytic anemia, or need for administration of any antibiotic or non-steroidal anti-inflammatory drugs were excluded from the study.

2.2 Methods

The patients were randomly divided into two groups. The first group received clarithromycin 500 mg PO bid and amoxicillin 500 mg PO bid for 2 weeks, in addition to omeprazole 20 mg PO bid for 6-8 weeks. The second group was given furazolidone 100 mg PO bid and amoxicillin 500 mg PO bid for 2 weeks, as well as omeprazole 20 mg PO bid for 6-8 weeks.

The patients were evaluated for eradication of H- pylori 2 weeks after ending of the study by urea breath test (UBT).

The study had been approved by local ethical committee of Qazvin's university of medical sciences. The patients provided written informed consent for participation in the study.

The collected data were analyzed by T-test and chi-square test using SPSS statistical software version 16.0.

3. Results

Fifty nine patients were allocated to the first group and sixty one patients were assigned into the second group. All the patients ended their instructed drug regimen and no loss of follow up were seen. Moreover, no disturbing adverse effects of the drugs were reported by the patients. The general characteristics of the groups were demonstrated in Table 1.

Table 1. The general characteristics of the studied groups

Age (years)		**Group 1**	**Group 2**	**P value**
		41.51±12.11	41.33±13.52	Not significant
Gender	male	25	25	Not significant
	female	34	36	
Level of education	High school	41	36	Not significant
	Bachelor degree	18	21	
	Higher than bachelor degree	0	4	
Symptoms	Epigastric burning pain	6	7	Not significant
	Abdominal pain	32	33	
	Epigastric fullness	21	21	
Diagnosis	Non-ulcer dyspepsia (NUD)	48	42	Not significant
	Peptic ulcer (PU)	11	19	